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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,520	04/20/2004	Charles Bryan Byrd	1380-028	2759

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EXAMINER	
KISH, JAMES M	
ART UNIT	**PAPER NUMBER**
3737	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/827,520	BYRD ET AL.
	Examiner	Art Unit
	JAMES KISH	3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 26-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 14-22 and 26* is/are rejected.

7)☒ Claim(s) *12,13,23,27 and 28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 14-20, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fife et al. (US Patent No. 4,534,221) – herein referred to as Fife – in view of Taimisto et al. (US Patent No. 7,396,332) – herein referred to as Taimisto. Fife

discloses an ultrasonic diagnostic imaging system wherein as the depth of focus is varied between near and far field focusing under operator control, the nominal frequency of the transmitted ultrasound energy is varied correspondingly by the system (*see* Abstract). A joystick may be used as an interface for receiving user input. A CPU and memory unit (i.e., a controller) changes transmit control information whenever the operator adjusts the joystick control for a significantly different depth of focus (column 4, lines 23-29). This altering of the frequency occurs automatically as the depth of focus is changed under operator control (column 1, lines 61-68 – at which Fife describes that "as the depth of focus is increased from near field focusing to far field focusing under operator control, the frequency of the transmitted ultrasonic energy is automatically reduced correspondingly," thereby teaching an operator performing a scanning of frequencies). However, Fife does not teach this system as being coupled to a catheter-based ultrasound probe. Taimisto teaches a transducer with multiple resonant frequencies for an imaging catheter. A first aspect of the invention involves an ultrasonic imaging catheter assembly including a catheter body and at least a single transducer element that is capable of oscillation at a plurality of natural resonant frequencies (column 1, line 60 through column 2, line 2). However, the catheter could even use a plurality of multiple resonant frequency transducers (column 3, lines 54-60). A number of external instrument consoles (i.e., interfaces) are contemplated for use to allow switching between various frequencies (column 5, lines 5-8). One example of imaging frequencies to be used includes 7.5 MHz and 10 MHz, which are both within a range of about 2 MHz to about 20 MHz. It would have been obvious to one of ordinary

skill in the art at the time the invention was made to utilize an ultrasound catheter, such as that taught by Taimisto, as the delivery device for the controller of Fife because in order to assist physicians and staff performing diagnostic and therapeutic procedures, a number of ultrasonic imaging system have been designed for use with catheters (column 1, lines 18-20 of Taimisto).

The system of Fife determines the frequency based on the imaging depth. Table I illustrates different frequencies (in MHz) that correspond to different depths (in centimeters). Using the proper mathematics, a change from 2.0 cm to 12.5 cm is a difference of 10.5 cm and the frequency changes a total of 2.5 MHz between those depths, therefore, 2.5 MHz divided by 10.5 cm provides for a change of approximately 0.24 MHz per 1.0 cm. This is assuming a consistent attenuation between 2.0 and 12.5 cm, and using values on the 3.5 MHz transducer column of this Table. So if the operator changes the depth by whole centimeters the increment is 0.24 MHz, which is *about* 0.5 MHz. However, some of the depths are, for example, 6.5 cm. Therefore, if the operator changes the depth by offsets of 0.5 centimeters the increment is 0.12 MHz, which is *about* 0.1 MHz. The increment by which the system would change frequencies would be a matter of design choice based on the increments by which the depth changes.

Regarding claims 7 and 20, Fife describes that “as the depth of focus is increased from near field focusing to far field focusing under operator control, the frequency of the transmitted ultrasonic energy is automatically reduced correspondingly,” thereby teaching an operator performing a scanning of frequencies. It

is obvious that the system would be required to determine the next frequency in order for the system to switch to the next frequency as the operator changes from the near field to the far field.

Claims 8 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fife in view of Taimisto as applied to claim 1 above, and further in view of Yukov (US Patent No. 5,361,767). Fife in combination with Taimisto is previously described with respect to claims 1 and 14. However, there is no thorough description as to how the interrogation depth is determined. Yukov teaches a B-mode imaging system that provides the operator with a control panel of image processing options. The control panel unit may include any suitable means known in the art for allowing an operator to select regions of interest On the image. For example, the control panel may include means for positioning digital calipers against the image to measure the size, depth and/or thickness (column 6, lines 14-30). Furthermore, the apparatus comprises a system for manually and/or automatically analyzing tissue matter to ascertain the nature of the tissue and/or its state (column 5, lines 65-68). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to allow an operator to select a region of interest on an image, determine the depth and provide the best frequency based on the depth, as disclosed by the combination of Fife and Taimisto with Yukov.

Claims 3, 6-7, 9, 11, 16, 19-20, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fife in view of Taimisto as applied to claim 1 above, and further in view of Passi et al. (US Patent No. 6,322,507) – herein referred to as Passi. Fife in combination with Taimisto is previously described with respect to claims 1 and 14. However, the frequency is not said to be determined as compared to a predicted attenuation. Passi teaches a method and system for ultrasonic imaging of bone tissue. However, a particular feature of the ultrasonic apparatus of Passi incorporates a digital computing device that includes a frequency selection mechanism, by which the user of the apparatus may select a frequency at which ultrasonic pulses are to be transmitted (column 11, lines 48-52). The frequency selection mechanism can also receive input from components of digital computing device (such as wave form analyzing mechanisms) which can automatically determine the frequency at which ultrasonic pulses are to be transmitted (column 11, lines 56-62). Column 12 through column 13, line 18 describe the possible factors for the frequency selection. Attenuation and velocity are determined as described in this passage (also, *see* Abstract). A scan is provided in order to characterize the thickness of the tissue being imaged, in the example of Passi this tissue is bone. It would be obvious to one of ordinary skill in the art to incorporate the attenuation measurements into the determination of the transmit frequency, as taught by Passi, in order to determine the depths upper and lower limits for a particular area or tissue of interest, thereby optimizing the image quality for that area (column 13, lines 13-19), whether the area be bone or cardiac tissue.

With regard to claims 3, 11 and 16, at column 12, lines 32-64, Passi describes that an initial transmission parameter is determined manually and empirically by an operator. Upon transmission of the wave, a full wave quantity counting mechanism and waveform analyzing mechanism evaluate the received signal and instruct the frequency selection mechanism to change the frequency of the transmitted pulse by 0.1 MHz. Specifically, “if the received pulse does not contain the same number of full waves as the transmitted pulse (column 12, lines 44-46)” teaches that attenuation would remove full waves (or periods) with the known value any number of full waves differing than that which was transmitted. It would be obvious to one of ordinary skill in the art to incorporate the attenuation measurements into the determination of the transmit frequency, as taught by Passi, in order to determine the depths upper and lower limits for a particular area or tissue of interest, thereby optimizing the image quality for that area (column 13, lines 13-19), whether the area be bone or cardiac tissue.

Regarding claims 3, 6-7, 16, 19-20 as being doubly rejected within the above paragraphs and the original rejection based solely on Fife and Taimisto, the Examiner believes these limitations to be obvious in view solely of Fife and Taimisto. However, the subject matter of these claims are also found in the disclosure of Passi and thereby is the reason for these claims being doubly rejected.

Claims 9 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fife in view of Taimisto as applied to claims 1 and 14 above, and further in view of Erikson et al. (US Patent No. 5,301,674) – herein referred to as Erikson. Fife in

combination with Taimisto is previously described with respect to claim 1. However, the signal attenuation is not factored in to the frequency selection process of Fife or Taimisto. Erikson teaches an ultrasound imaging system for performing dynamic focusing of ultrasonic waves during transmit and receive. The system optimizes the transmit frequency for each of multiple depths to localize the energy of the ultrasonic wave (*see* Abstract). Column 15, line 13 through column 17, line 10 describes methods that can be used to determine the proper transmit frequency. The second equation, f_{amp}, is the estimation. The term, α in this equation is the attenuation parameter (*see* column 16, line 35). Therefore, the system optimizes the transmit frequency based on several parameters, including the attenuation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to factor the attenuation of the tissue being scanned in order to optimize the transmit frequency to provide for the best drop-off characteristics for the pulse after the zone [or depth of interest] (column 15, lines 23-25).

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fife in view of Taimisto and either one of Passi and Erikson as each is applied to claim 9 above, and further in view of any one of Nachtomy et al. (US Patent No. 6,095,976) – herein referred to as Nachtomy – or Swanson et al. (US Patent App. No. 2001/0020126) – herein referred to as Swanson – or Kuban et al. (US Patent No. 2004/0039286) – herein referred to as Kuban. Fife in combination with Taimisto and either one of Passi and Erikson is previously described with regard to claim 9. However, while Taimisto

teaches that the ability to change the depth of field is beneficial for imaging the heart (*see* column 2, lines 25-29 and column 4, lines 28-41), there is no explicit teaching of correlating the imaging to an electrocardiogram (ECG).

Nachtomy teaches that it is well-known in the art that cardiac gating is performed by using an external signal, usually an ECG and requires that both the acquisition of the ECG signal and its interleaving (or synchronization) with an intravenous ultrasound image (column 2, lines 58-68).

Swanson teaches that when a catheter is used to acquire ultrasound imaging inside a beating heart chamber, a stepper motor is preferably gated by a gating circuit to the QRS of an ECG taken simultaneously with image gathering (paragraph 103).

Kuban teaches that by identifying a cyclical portion of the heartbeat data and acquiring blood-vessel data during this cyclical portion, the blood vessel can be analyzed as if it were standing still. The heart-monitoring device includes an ECG and the data-gathering device includes an intravascular ultrasound device (*see* Abstract).

Therefore, it is well-known in the art at the time the invention was made to gate the image acquisition to an ECG when imaging the heart, which is contemplated by Taimisto.

Allowable Subject Matter

Claims 12-13, 23, 27-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES KISH whose telephone number is (571)272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit 3737

JMK